OCT 2 1 2003

Special 510 (k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K032985

Introduction: According to the requirements of 21 CFR 862.1345, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter: HMD BIOMEDICAL, Inc.

Address: 3 F, No. 324, Sec. 1, Chunghwa Rd. Hsinchu, Taiwan, 300

Contact Number: Phone: 886-3-5354630
Fax: 886-3-5354633

Contact Person: Jeffery Fleishman
Official Correspondent

Date Prepared: Sep.10.2003

Device Name:

Proprietary name: GlucoLeader™ Enhance Self-Monitoring of Blood Glucose System

Common name: Glucose Meter

Classification name: NBW (System, Test Blood Glucose, over the Counter)

Device Classification: Glucose Test System per21 CFR 862.1345
Class II Device

Predicate Device:

Name: GlucoLeaderTM Value Self-Monitoring of Blood Glucose System

Manufacturer: HMD BioMedical Inc.
3 F, No. 324, Sec. 1, Chunghwa Rd. Hsinchu, Taiwan, 300

510(k) Number: K023279

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Test Principle:

The GlucoLeader™ Enhance Self-Monitoring of Blood Glucose System is comprised of two main parts a bio-active electrode (test strip) containing the enzyme glucose oxidase and the glucose meter. The blood sample is drawn into the Test Strip through capillary action. Glucose in the sample reacts with glucose oxidase and potassium ferricyanide in the strip, producing potassium ferrocyanide. Potassium ferrocyanide is produced in proportion to the glucose concentration of the blood sample .Oxidation of the potassium ferrocyanide produces an electrical current which is then converted by the meter to display the glucose concentration.

Intended Use:

The GlucoLeader Enhance Self-Monitoring of Blood Glucose System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, this device is not suitable for neonate samples.

Similarities:

The proposed modification is relatively modest in scope. All of the following are claims and features unaffected by the proposed modification

Feature/Claim	Detail
Intended Use	The GlucoLeader Enhance Self-Monitoring of Blood Glucose System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, this device is not suitable for neonate samples.
Test Principle	The GlucoLeader Enhance Self-Monitoring of Blood Glucose System is base on the measurement of electrical current caused by the reaction of glucose with the reagent (Glucose Oxidase method) on the electrode of the strip.
Warnings and Precautions	For *in-vitro* diagnostic use only
Specimen Type	Capillary whole blood
Sample volume	Both need 3uL capillary whole blood

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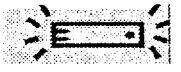
Measuring Time	Both within 15 seconds
System Performance	Both use two levels quality control solution to check system performance.
Measuring Range	Both in 30~600 mg/dL
Acceptable Hematocrit Range	30-50 %

Differences:

Feature	**GlucoLeader™ Enhance Self-Monitoring of Blood Glucose System (modified)**	**GlucoLeader™ Value Self-Monitoring of Blood Glucose System (predicate)**
Meter Dimension	95 (L)*60 (W)*18.5(H)mm	93(L)*38(W)*18(H)mm
Weight	Approximate 70g (with battery)	Approximate 30g(with battery)
Electrics voltage	0.15V	0.41V
Measuring current limited	50μA	75μA
Button	Left: Function key Right: Memory, Setting key	No button
Setting function	Setting date, time and unit	NA
Data download	Test results can download by RS232 interface	NA
Average result with memory	Calculate mean results within 7,14,21and 28 days	NA
Ready to test symbol.	User can apply blood to the strip after the  display on LCD.	User can apply blood to the strip after the 「bLd」 display on LCD
Flashing strip symbol	Press any button to power on, the code number and  will display	NA

The detail differences listing are shown on "Substantial Equivalent Table".

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Data Demonstrating substantial equivalence:

The results conducted at consumer and point-of-care studies demonstrated consistent quality performance of. GlucoLeader™ Enhance Self-Monitoring of Blood Glucose System. These study demonstrated good correlation(R>0.98) between 40~400 mg/dl of capillary whole blood specimens. With these data it is proved that the regression analysis of the system is equivalent predicate device

Consumer Study

Linear regression between GlucoLeader Enhance (GEB) and YSI for lay users and technician

Accuracy of lay users compared to YSI using capillary whole blood on 180 specimens at clinical centers	N=180 Y= 0.9684X+2.3058 R=0.987 Sy.x=13.65205 Range=64-539mg/dL
Accuracy of technician compared to YSI using capillary whole blood on 180 specimens at clinical centers	N=180 Y= 0.9934X-2.3866 R=0.981 Sy.x=19.0268 Range=68-539mg/dL

Point-Of-Care Study

Linear regression between GlucoLeader Enhance (GEB) and GlucoLeader Value (GVA) for test on department of Home Medical, Internal, and Metabolism

Home Medical	Metabolism	Internal	Total
N=50	N=50	N=50	N=150
Y= 0.969X+6.82	Y= 0.9168X+8.87	Y= 0.9982X-6.57	Y= 0.9573X+4.37
R=0.989	R=0.986	R=0.982	R=0.986
Sy.x=12.65	Sy.x=10.36	Sy.x=16.49	Sy.x=13.78
Range=68-388mg/dL	Range=71-298mg/dL	Range=72-411mg/dL	Range=68-411mg/dL

Conclusion:

According to the tests consisted of system function, hardware, software, packaging, electrical safety and laboratory, clinical evaluations, these design modified can be verified and validated demonstrating that the performance of the GlucoLeader™ Enhance Self-Monitoring of Blood Glucose System will not affected safety and effectiveness.

Test demonstrated that the performance of the GlucoLeader™ Enhance Self-Monitoring of Blood Glucose System was substantially equivalent to predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 21 2003

HMD BIOMEDICAL, INC.
c/o Mr. Jeffery Fleishman
Official Correspondent
Immunostics, Inc.
3505 Sunset Avenue
Ocean, NJ 07712

Re: k032985
Trade/Device Name: GlucoLeader™ Enhance Self-Monitoring of Blood Glucose System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; CGA
Dated: September 22, 2003
Received: September 24, 2003

Dear Mr. Fleishman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K032985 SPECIAL

Device Name:

GlucoLeader™ Enhance Self-Monitoring of Blood Glucose System

Indications for Use: The GlucoLeader Enhance Self-Monitoring of Blood Glucose System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in a clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control.

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032985 SPECIAL

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓

(Per 21 CFR 801.109)